



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,794	05/24/2007	Abdessatar Chitourou	REGIM 3.3-093	5868
530 7590 11/20/2009 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER				
TSAY, MARSHA M				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
11/20/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/576,794

**Applicant(s)**

CHTOUROU ET AL.

**Examiner**

Marsha M. Tsay

**Art Unit**

1656

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 11-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 11-15 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 09.26.08

Applicant's election of Group III, claims 7-9, 16-17, in the reply filed on September 17, 2009, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 10 is canceled. Claims 1-6, 11-15, 18 have been withdrawn from further consideration by the Examiner because they are drawn to non-elected inventions. Claims 7-9, 16-17 are currently under examination.

Priority: The request for priority to FRANCE 0312398, filed October 23, 2003, is acknowledged. A certified copy of the foreign priority document has been filed in this case on April 21, 2006 and is in a non-English language.

### ***Claim Objections***

Claims 7, 16-17 are objected to because of the following informalities: in claim 7, the term "vWF" should be spelled out the first time that it is recited in the claim(s); in claims 16-17, the term "ore" should be corrected to "or." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9, 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites filtering a solution. It is unclear whether or not the solution contains FVIII. Claim 7 recites high-multimerization vWF. It is unclear what is meant by "high-multimerization" vWF. Also, the preamble of claim 7 recites preparing a virally safe FVIII solution; so it is unclear what the relationship between "assaying the filtrate to determine high multimerization vWF" and "virally safe FVIII solution" is. Right now, the claim does not recite the essential step that is necessary to prepare the virally safe FVIII solution.

Claims 9, 16-17 recite 24 to 30 nm. It is unclear if "nm" is referring to the diameter of the virus or not. Further clarification is requested. Also, it is unclear how the viruses having size 24-30 nm is screened for since the preamble of claim 7 does not specify the virus size. It is also unclear how a vWF decamer and/or multimer content less than 15% indicates that the titre reduction factor is 4 log to about 6 log.

Claim 17 recites that the titre reduction factor is 6 log or more to about 6 log. This phrase does not make sense because it is unclear whether or not there is an upper limit to the titre reduction factor. Further clarification is requested.

Claim 8 is included in this rejection because it is dependent on claim 7.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-9, 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chtourou et al. (US 6967239).

The applied reference has 2 common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

For examination purposes, the instant claims have been interpreted as a method for preparing a virally safe FVIII solution comprising filtering a solution containing FVIII through nanometric filters having a pore size of 13 nm to about 25 nm and assaying the filtrate to determine the residual content of high-multimerization vWF.

Chtourou et al. teach a method for preparing a FVIII solution comprising filtering a FVIII solution through a virus filter that has a mean pore size of 13 to 17 nm and wherein the filtered FVIII solution is free of viruses and devoid of high molecular forms of vWF and FVIII-vWF complexes (col. 10 lines 5-19; claims 7-9, 16-17). Chtourou et al. teach a chromatographic step after virus inactivation in order to determine the vWF content and vWF multimer profile (col. 1 example 1, col. 9 example 7). Regarding the limitations of claims 9, 16-17 (i.e. the titre reduction factor), it is believed that said limitations are anticipated by Chtourou et al. since

Chtourou et al. teach the instant active step of filtering a FVIII solution through filters having the instant pore size, as well as teach the instant limitation that the vWF multimer content is less than 15%.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/  
Primary Examiner, Art Unit 1656

November 16, 2009

Marsha Tsay  
Art Unit 1656